WHAT IS CLAIMED IS

1. A method for sterilizing a biological material that is sensitive to radiation, said method comprising irradiating said biological material with radiation for a time effective to sterilize said biological material at a rate effective to sterilize said biological material and to protect said biological material from said radiation.

2. A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said radiation;

(b) reducing the residual solvent content of said biological material to a level effective to protect said biological material from said radiation;

(c) reducing the temperature of said biological material to a level effective to protect said biological material from said radiation;

(d) reducing the oxygen content of said biological material to a level effective to protect said biological material from said radiation;

(e) adjusting the pH of said biological material to a level effective to protect said biological material from said radiation; and

(f) adding to said biological material at least one non-aqueous solvent in an amount effective to protect said biological material from said radiation;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material.

3. A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer;

(b) reducing the residual solvent content of said biological material;

(c) reducing the temperature of said biological material;

(d) reducing the oxygen content of said biological material;

(e) adjusting the pH of said biological material; and

(f) adding to said biological material at least one non-aqueous solvent;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said at least one stabilizing process and the rate of irradiation are together effective to protect said biological material from said radiation.

4. A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer;

(b) reducing the residual solvent content of said biological material;

(c) reducing the temperature of said biological material;

(d) reducing the oxygen content of said biological material;

(e) adjusting the pH of said biological material; and

(f) adding to said biological material at least one non-aqueous solvent;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said at least two stabilizing processes are together effective to protect said biological material from said radiation and further wherein said at least two stabilizing processes may be performed in any order.

5. The method according to claim 2, 3 or 4, wherein said residual solvent is an organic solvent.

6. The method according to claim 1, 2, 3 or 4, wherein said effective rate is not more than about 3.0 kGy/hour.

7. The method according to claim 1, 2, 3 or 4, wherein said effective rate is not more than about 2.0 kGy/hr.

8. The method according to claim 1, 2, 3 or 4, wherein said effective rate is not more than about 1.0 kGy/hr.

9. The method according to claim 1, 2, 3 or 4, wherein said effective rate is not more than about 0.3 kGy/hr.

10. The method according to claim 1, 2, 3 or 4, wherein said effective rate is more than about 3.0 kGy/hour.

11. The method according to claim 1, 2, 3 or 4, wherein said effective rate is at least about 6.0 kGy/hour.

12. The method according to claim 1, 2, 3 or 4, wherein said effective rate is at least about 18.0 kGy/hour.

13. The method according to claim 1, 2, 3 or 4, wherein said effective rate is at least about 30.0 kGy/hour.

14. The method according to claim 1, 2, 3 or 4, wherein said effective rate is at least about 45 kGy/hour.

15. The method according to claim 1, 2, 3 or 4, wherein said biological material is maintained in a low oxygen atmosphere.

16. The method according to claim 1, 2, 3 or 4, wherein said biological material is maintained in an atmosphere comprising at least one noble gas or nitrogen.

17. The method according to claim 16, wherein said noble gas is argon.

18. The method according to claim 1, 2, 3 or 4, wherein said biological material is maintained in a vacuum.

19. The method according to claim 2, 3 or 4, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying and vitrification.

20. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 15%.

21. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 10%.

22. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 3%.

23. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 2%.

24. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 1%.

25. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 0.5%.

26. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 0.08%.

27. The method according to claim 1, 2, 3 or 4, wherein at least one sensitizer is added to said biological material prior to said step of irradiating said biological material.

28. The method according to claim 1, 2, 3, or 4, wherein said biological material contains at least one biological contaminant or pathogen selected from the group consisting of viruses, bacteria, yeasts, molds, fungi, parasites and prions or similar agents responsible, alone or in combination, for TSEs.

29. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is an antioxidant.

30. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is a free radical scavenger.

31. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is a combination stabilizer.

32. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is a ligand.

33. The method according to claim 32, wherein said ligand is heparin.

34. The method according to claim 2, 3 or 4, wherein said at least one stabilizer reduces damage due to reactive oxygen species.

35. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; vitamin E or a derivative thereof; albumin; sucrose; glycylglycine; L-carnosine; cysteine; silymarin; diosmin; hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; ethanol; acetone; rutin; epicatechin; biacalein; purpurogallin; and mixtures of two or more thereof.

36. The method according to claim 35, wherein said mixtures of two or more additional stabilizers are selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid and mixtures of uric acid, or a salt or

ester thereof; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

37. The method according to claim 2, 3 or 4, wherein said at least one stabilizer is a dipeptide stabilizer.

38. The method according to claim 37, wherein said dipeptide stabilizer is selected from the group consisting of glycyl-glycine (Gly-Gly), carnosine and anserine.

39. The method according to claim 1, 2, 3 or 4, wherein said radiation is corpuscular radiation, electromagnetic radiation, or a mixture thereof.

40. The method according to claim 39, wherein said electromagnetic radiation is selected from the group consisting of radio waves, microwaves, visible and invisible light, ultraviolet light, x-ray radiation, gamma radiation and combinations thereof.

41. The method according to claim 1, 2, 3 or 4, wherein said radiation is gamma radiation.

42. The method according to claim 1, 2, 3 or 4, wherein said radiation is E-beam radiation.

43. The method according to claim 1, 2, 3 or 4, wherein said radiation is visible light.

44. The method according to claim 1, 2, 3 or 4, wherein said radiation is ultraviolet light.

45. The method according to claim 1, 2, 3 or 4, wherein said radiation is x-ray radiation.

46. The method according to claim 1, 2, 3 or 4, wherein said radiation is polychromatic visible light.

47. The method according to claim 1, 2, 3 or 4, wherein said radiation is infrared.

48. The method according to claim 1, 2, 3 or 4, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

49. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted at ambient temperature.

50. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted at a temperature below ambient temperature.

51. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted below the freezing point of said biological material.

52. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted below the eutectic point of said biological material.

53. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted at a temperature above ambient temperature.

54. A composition comprising at least one biological material and at least one stabilizer in an amount effective to preserve said biological material for its intended use following sterilization with radiation.

55. A composition comprising at least one biological material, wherein the residual solvent content of said biological material is at a level effective to preserve said biological material for its intended use following sterilization with radiation.

56. The composition of claim 55, wherein said residual solvent content is less than about 15%.

57. The composition of claim 55, wherein said residual solvent content is less than about 10%.

58. The composition of claim 55, wherein said residual solvent content is less than about 5%.

59. The composition of claim 55, wherein said residual solvent content is less than about 2%.

60. The composition of claim 55, wherein said residual solvent content is less than about 1%.

61. The composition of claim 55, wherein said residual solvent content is less than about 0.5%.

62. The composition of claim 55, wherein said residual solvent content is less than about 0.08%.

63. The composition of claim 54 or 55, wherein said biological material is glassy or vitrified.

64. The composition of claim 54 or 55, wherein the concentration of said biological material in said solvent is at least about 0.5%.

65. The composition of claim 54 or 55, wherein the concentration of said biological material in said solvent is at least about 1%.

66. The composition of claim 54 or 55, wherein the concentration of said biological material in said solvent is at least about 5%.

67. The composition of claim 54 or 55, wherein the concentration of said biological material in said solvent is at least about 10%.

68. The composition of claim 54 or 55, wherein the concentration of said biological material in said solvent is at least about 15%.

69. The composition of claim 54 or 55, wherein the concentration of said biological material in said solvent is at least about 20%.

70. The composition of claim 54 or 55, wherein the concentration of said biological material in said solvent is at least about 25%.

71. The composition of claim 54 or 55, wherein the concentration of said biological material in said solvent is at least about 50%.

72. The method according to claim 2, 3 or 4, wherein said non-aqueous solvent is selected from the group consisting of glycerol, DMSO, ethanol, acetone and PPG, and mixtures thereof.

73. The method according to claim 72, wherein said PPG is PPG 400, PPG 1200 or PPG 2000.

74. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 0%.

75. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 1%.

76. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 2.4%.

77. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 4.8%.

78. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 7%.

79. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 9%.

80. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 10%.

81. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 20%.

82. The method according to claim 2, 3 or 4, wherein said residual solvent content is about 33%.

83. The method according to claim 2, 3 or 4, wherein said residual solvent content is less than about 33%.

84. The composition of claim 56, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; vitamin E or a derivative thereof; albumin; sucrose; glycylglycine; L-carnosine; cysteine; silymarin; diosmin;

hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; ethanol; acetone; rutin; epicatechin; biacalein; purpurogallin; and mixtures of two or more thereof.

85. The composition of claim 84, wherein said mixtures of two or more additional stabilizers are selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid and mixtures of uric acid, or a salt or ester thereof; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

86. A method for prophylaxis or treatment of a condition or disease in a mammal comprising administering to a mammal in need thereof an effective amount of a biological material made according to a method of one of claims 1, 2, 3 or 4.

87. The method according to claim 1, 2, 3 or 4, wherein said biological material is selected from the group consisting of dextrose, urokinase, thrombin, trypsin, purified protein fraction, blood, blood cells, alpha 1 proteinase inhibitor, digestive enzymes, blood proteins and tissue.

88. The method according to claim 87, wherein said tissue is selected from the group consisting of heart valves, ligaments and demineralized bone matrix.

89. The method according to claim 2, 3 or 4, wherein said residual solvent is an aqueous solvent.

90. The method according to claim 2, 3 or 4, wherein said biological material is suspended in said solvent.

91. The method according to claim 2, 3 or 4, wherein said biological material is dissolved in said solvent.

92. The method according to claim 1, 2, 3 or 4, wherein said irradiation is conducted below the glass transition point of said biological material.

93. A method for prophylaxis or treatment of a condition or disease in a mammal comprising administering to a mammal in need thereof an effective amount of a composition of claim 54 or 55.

94. The method according to claim 87, wherein said digestive enzymes are selected from the group consisting of galactosidases and sulfatases.

95. The method according to claim 87, wherein said blood proteins are selected from the group consisting of albumin, Factor VIII, Factor VII, Factor IV, fibrinogen, monoclonal immunoglobulins and polyclonal immunoglobulins.

96. The method according to claim 87, wherein said tissue is selected from the group consisting of tendons, nerves, bone, teeth, bone marrow, skin grafts, cartilage, corneas, arteries, veins and organs for transplantation.

97. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is greater than 100% of the pre-irradiation value.

98. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 100% of the pre-irradiation value.

99. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 90% of the pre-irradiation value.

100. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 80% of the pre-irradiation value.

101. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 70% of the pre-irradiation value.

102. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 60% of the pre-irradiation value.

103. The method according to claim 1, 2, 3 or 4, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 50% of the pre-irradiation value.